SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Trade Name: TANITA Ironman Innerscan Body Composition Monitor: Model BC-558
Common Name: Segmental Body Composition Monitor
Classification Name: ANALYZER, BODY COMPOSITION 21 CFR §807.92

DEC 2 8 2006

Description of Applicant Device:

The TANITA Ironman Innerscan Body Composition Monitor BC-558 are a computer-operated body composition analyzer that utilizes BIA (bioelectrical impedance analysis) to determine body fat percent, muscle mass, bone weight, visceral fat rating, Basal Metabolic Rate (BMR), metabolism age, physique rating, daily calorie intake (DCI), body water percent and segmental fat percent.

Intended Uses of Applicant Device:

The TANITA Ironman Innerscan Body Composition Monitor measures body weight, impedance and estimates total and segmental body fat percentage, body water, total and segmental muscle mass, physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate(BMR), daily caloric intake(DCI) and metabolic age using BIA (Bioelectrical Impedance Analysis). The device is intended to be used by generally healthy children 7-17 years old and generally healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.

Actual measurements made by the BC-558 include weight and impedance. Based upon these measured values, values are calculated for: total and segmental body fat percentage, body water, total and segmental muscle mass, physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate (BMR), daily caloric intake (DCI) and metabolic age.

Predicate Devices:

TANITA Body Fat Analyzer Professional and Consumer Models K040778 and K033157

Scientific Concepts and Significant Performance Characteristics:

*Same as shown in SECTION 9. and APPENDIX 1. (Substantial Equivalence Matrix)

		New BC-558 Specification	Predicate Device#: K040778 BC-53X Specification	Predicate Device#: K033157 BC-418 Specification
Product Description		Body composition monitor/scale that utilizes a segmental BIA technology to determine internal body composition.	Body composition monitor/scale that utilizes a "foot-to-foot" BIA technology to determine internal body composition.	Body composition monitor/scale that utilizes a segmental BIA technology to determine internal body composition.
Analytical Method / Measurement		Segmental BIA In house BIA and DXEA reference	Foot-to Foot BIA In house BIA and DXEA/Deuterium Dilution reference	Segmental BIA In house BIA and DXEA reference
Measurement Frequency		50kHz	50kHz	50kHz
Measurement Current		Max. 500μA	Max. 500μA	Max. 90 μA
Number of Electrodes		8	4	8
Specifications				
Capacity		150 kg / 330 lb	150 kg / 330 lb	200 kg / 440 lb
Increments		100 g / 0.2 lb or 50 g / 0.1 lb	100 g / 0.2 lb	100 g / 0.2 lb
Body Fat %		0.1%	0.1%	0.1%
User Memory		4	4	-
Input Age		7 - 99	7 - 99	7 - 99
		7-17: Child	7-17: Child	7-17: Child
		18-99: Adult	18-99: Adult	18-99: Adult
Input Height		90cm~220cm	100 cm - 220 cm	90 cm - 249 cm
Input Activity Level		1 - 3	1 - 3	-
Input Body Type		Standard / Athlete	Standard / Athlete	Standard / Athlete
Data Memory		31days / 1day average	-	-
		52weeks / 1week average	4weeks / 1week average	
		36months / 1month average	2months / 1month average	
Power Supply		AA Batteries	AA Batteries	AC Adapter / DC5V 3.5A
Printer Function		-	-	✓
Conputer Interface		-	-	RS-232
Functions				
Weight		✓	✓	✓
Body Fat %	Full body	✓	✓	✓
	Right arm	✓	-	✓
	Left arm	✓	-	✓
	Right feet	✓	-	✓
	Left feet	✓	-	✓
	Trunk	✓	-	✓
% Fat Judge		✓	✓	✓
Body Water%		✓	✓	-
Muscle Mass	Full body	✓	✓	✓
	Right arm	✓	-	✓
	Left arm	✓	-	✓
	Right feet	✓	-	✓
	Left feet	✓	-	✓
	Trunk	✓	-	✓
Physique Rating		✓	✓	-
Bone mass		✓	✓	-
Visceral Fat		✓	✓	-
Visceral Fat Judge		✓	✓	-
BMR		✓	✓	✓
DCI		✓	✓	-
Metabolic Age		✓	✓	-
BMI		✓	-	✓

510(k) SUMMARY

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Side by side comparison of the TANITA Ironman Innerscan Body Composition Monitor BC-558 to the predicate devices clearly demonstrates that the applicant devices are substantially equivalent to those legally marketed devices.

Based on the results of using the previously approved BIA methodology with our whole body BIA, it was concluded that the TANITA Ironman Innerscan Body Composition Monitor BC-558 performs as well as the predicate devices and therefore have proven its safety and efficacy.

Beth Mackey
TANITA Corporation of America
Marketing Director

Tel: (847)434-3981
Fax: (847)640-7978

July 7, 2006
Revised in red: December 14, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC 2 8 2006

Ms. Beth Mackey
Marketing Director
TANITA Corporation of America, Inc.
2625 South Clearbrook Drive
ARLINGTON HEIGHTS IL 60005

Re: K062652
Trade/Device Name: TANITA Ironman Innerscan Body Composition Monitor
Model BC-558
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: December 14, 2006
Received: December 15, 2006

Dear Ms. Mackey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 062652

Device Name: TANITA Ironman Innerscan Body Composition Monitor Model BC-558

Indications For Use: The TANITA Ironman Innerscan Body Composition Monitor measures body weight, impedance and estimates total and segmental body fat percentage, body water, total and segmental muscle mass, physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate(BMR), daily caloric intake(DCI) and metabolic age using BIA (Bioelectrical Impedance Analysis). The device is intended to be used by generally healthy children 7-17 years old and generally healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.

Actual measurements made by the BC-558 include weight and impedance. Based upon these measured values, values are calculated for: total and segmental body fat percentage, body water, total and segmental muscle mass, physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate (BMR), daily caloric intake (DCI) and metabolic age.

Prescription Use _____ AND/OR Over-The-Counter Use ___x___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062652